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## **Declaration of Dr. Albert C. Wehl, M.D.**

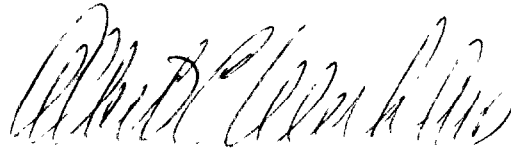
I, Albert C. Wehl, M.D., hereby submit this declaration in order to provide information about the use of Adenocard® (adenosine injection) in the emergency room and ambulance settings. I have extensive experience in the use and administration of Adenocard® as well as with emergency room and ambulance practices. I am Board certified by, among others, the American Board of Emergency Medicine and the American Board of Internal Medicine. I am an Oral Board Examiner for the American Board of Emergency Medicine. My C.V. is attached hereto as Appendix A.

I hereby declare as follows:

1. I am familiar with the drug Adenocard®, which is indicated for conversion to sinus rhythm of paroxysmal supraventricular tachycardia (PSVT), including that associated with accessory bypass tracts (Wolff-Parkinson-White Syndrome). Adenocard® is primarily used in an emergency room or ambulance setting. In most cases, need for the product is sudden, and speed of administration is critical.
2. The Adenocard® label describes administering up to three doses of Adenocard® to patients for the treatment of PSVT. The label recommends a third dose -- of 12 mg -- only for patients who do not respond to the first two injections. However, in clinical practice, paramedics and emergency department personnel often switch to alternate treatment modalities if patients do not respond to one or two adenosine injections.
3. It is important in emergency situations to have the proper dose of adenosine prepared and ready to use. Adenocard®'s current strength and packaging is ideal for rapidly and reliably administering the correct dose of adenosine to patients. When emergency medical personnel need to administer Adenocard®, they simply unwrap a single prefilled syringe and administer its full contents to the patient. If a second dose is needed, a second full syringe is administered. The individual packaging virtually eliminates the possibility of dosing error.
4. Similarly, with the existing generic formulations of adenosine, the entire vial is drawn into the syringe and administered.

5. I have been informed that there is a proposal to package adenosine in 18 mg and 30 mg strength vials, labeled for treatment of PSVT. I have been asked whether vials of these strengths would be beneficial or useful. It is my opinion that such vials would not be useful in an emergency setting and would lead to waste and the potential for dosing errors.
6. With 18 mg and 30 mg strength vials, emergency room personnel and paramedics will be forced to measure out the proper dose (either 6 mg or 12 mg) from the vials before administering adenosine. In a critical situation, such as in a bumpy ambulance or in low light, this can easily result in dosing errors.
7. The proposed multidose vials would not be more efficient than current packaging because each single dose of adenosine would have to be drawn individually. I would warn against drawing up multiple doses of adenosine into a single syringe because adenosine is only effective in treatment of PSVT if administered as a rapid bolus. Although some drugs, such as lidocaine, can be slowly titrated into a patient by administering multiple doses from a single syringe, adenosine, because of its extremely short half life, is likely to be ineffective unless administered as a forceful rapid bolus. Indeed, in my experience, adenosine is practically unique in having to be administered extremely rapidly in order to be effective.
8. Therefore emergency room personnel and paramedics are trained to administer the drug with a pressure injection. Since these personnel are accustomed to administering the entire 6 mg or 12 mg vials or prefilled syringes, if a larger vial is used, there is a real possibility that they may mistakenly inject an entire 30 mg vial into a patient.
9. Such dosing errors may put patients at unnecessary risk of complications and adverse events such as hypotension, bronchospasm, or high-grade atrioventricular (AV) node block. For example, a period of prolonged asystole could be created by such a dosing error. A prolonged period of asystole could lead to other unneeded treatment such as atropine injection.
10. In my opinion, if these larger vials were available and used in the hospital emergency room, every nurse and paramedical unit would have to be extensively retrained in the use of the drug. Since generic manufacturers do not provide in-service training, the need for retraining should be placed as a box warning on these larger vials to avoid over dosage.
11. Even in a large emergency room practice such as mine, the need for adenosine is sporadic and limited, perhaps one or two times a month. Adenocard®, or currently available generic adenosine, is not sufficiently expensive to make the cost savings (if any) on the use of larger vials offset the costs of the necessary retraining.

I declare under penalty of perjury that the foregoing is true and correct, to the best of my knowledge, information, and belief. Executed on October 20, 2004, in Madison, Connecticut.

A handwritten signature in cursive script, appearing to read "Albert C. Wehl", written in black ink.

Albert C. Wehl, M.D.

## **CURRICULUM VITAE**

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**New Haven, Connecticut 06519**  
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**Date of Birth:** August 22, 1946, Cincinnati, Ohio

**Positions:**

**2004 - Present:** Assistant Clinical Professor  
Section of Emergency Medicine  
Departments of Surgery and Internal Medicine  
Yale University School of Medicine  
New Haven, Connecticut

**September 2002  
- June 2004:** Co-Director, Chest Pain Center  
Yale-New Haven Hospital  
New Haven, Connecticut

**December 2000  
-July 2001:** Acting Section Chief/Department Chair  
Section of Emergency Medicine/Department of Emergency Services  
Yale University School of Medicine/Yale-New Haven Hospital  
New Haven, Connecticut

**February 2000  
-September 2000:** Acting Residency Program Director  
Emergency Medicine Residency Program  
Yale-New Haven Medical Center  
New Haven, Connecticut

**1997- Present:** Oral Board Examiner  
American Board of Emergency Medicine

**1993 - 1998:** Residency Program Director  
Emergency Medicine Residency Program  
Yale-New Haven Medical Center  
New Haven, Connecticut

**1991 – 2004:** Assistant Professor  
Section of Emergency Medicine  
Departments of Surgery and Internal Medicine  
Yale University School of Medicine  
New Haven, Connecticut

**1991 – June 2004:**      **Educational Director**  
**Department of Emergency Services**  
**Yale-New Haven Hospital**

**1990 - 1998:**      **Assistant Medical Director**  
**Department of Emergency Services**  
**Yale New Haven Hospital**

**1989 - 1990:**      **Medical Director**  
**New Haven Sponsor Hospital Program**  
**Yale-New Haven Hospital/Hospital of Saint Raphael**

**1988 - 1990:**      **Acting Medical Director**  
**Department of Emergency Services**  
**Yale-New Haven Hospital**

**1987 - 1991:**      **Attending in Internal Medicine**  
**Department of Emergency Services**  
**Yale-New Haven Hospital**  
**New Haven, Connecticut**

**1982 - 2000**      **Emergency Department Physician**  
**Middlesex Hospital/Shoreline Clinic**  
**Middletown/Essex, Connecticut**

**1980 - 1991:**      **Assistant Clinical Professor**  
**Department of Internal Medicine**  
**Yale University School of Medicine**  
**New Haven, Connecticut**

**1982 - 1987:**      **Attending in Internal Medicine**  
**Hospital of Saint Raphael**  
**New Haven, Connecticut**

**1978 - present:**      **Attending Physician in Internal Medicine**  
**Yale-New Haven Hospital**  
**New Haven, Connecticut**

**1978 - 1987:**      **Physician, Department of Internal Medicine**  
**Community Health Care Plan**  
**150 Sargent Drive**  
**New Haven, Connecticut**

**1977 - 1978:**      **Associate Staff**  
**Department of Emergency Services**  
**Fairfax Hospital**  
**Falls Church, Virginia**

**1976 - 1978:** Lieutenant Commander, Medical Corps  
United States Naval Reserve  
Hyperbaric Medicine and Physiology Department  
Naval Medical Research Institute  
Bethesda, Maryland

**1975 - 1976:** Emergency Department Physician  
Winchester Hospital  
Winchester, Massachusetts

**1974 - 1976:** Clinical and Research Fellow  
Endocrine and Thyroid Units  
Massachusetts General Hospital

**1973 - 1974:** Senior Assistant Resident in Medicine  
Yale-New Haven Hospital

**1972 - 1973:** Junior Assistant Resident in Medicine  
Yale-New Haven Hospital

**1971 - 1972:** Intern in Medicine  
Yale-New Haven Hospital

**Degrees:**

**1971 M.D. Yale University School of Medicine**

**1967 B.S. Molecular Biophysics - Yale College**  
**Degree earned in three years**

**Professional Organizations:**

**1988 - present Society for Academic Emergency Medicine**

**1987 – 2004 American College of Emergency Physicians**

**1975 – 2004 American College of Physicians**

**1994 – 2001 American Medical Informatics Association**

**Board Certification:**

**1998        Re-certification, Diplomate, American Board of Emergency Medicine**

**1989        Diplomate, American Board of Emergency Medicine**

**1977        Diplomate, Subspecialty Board in Endocrinology and Metabolism**

**1974        Diplomate, American Board of Internal Medicine**

**1972        Diplomate, National Board of Medical Examiners**

**Licenses:**

**1992        Hawaii**

**1973        Connecticut**

**Committees and Boards:**

**September 2002        Co-Chairman, 5<sup>th</sup> Fifth National Congress of Chest Pain Centers  
Society of Chest Pain Centers and Providers  
New Haven, Connecticut**

**2001-2004              Claims Committee (Risk Management)  
Yale-New Haven Medical Center**

**2000-2004              Ethics Committee  
Yale-New Haven Medical Center**

**February 2000-  
September 2000        Graduate Medical Education Committee  
Yale-New Haven Medical Center**

**1998-present           Editorial Board  
Emergency Medicine Reports**

**1996- 1998             Chairman, Subcommittee on Medical-Legal Education  
Graduate Medical Education Committee  
Yale-New Haven Medical Center**

**1995 – 2004            Chairman, Clinical Computer Workstation Committee  
Yale-New Haven Medical Center**

**1995 - 1998            Graduate Medical Education Committee  
Yale-New Haven Medical Center**



<b>1995 - 1998</b>	<b>Computer Committee Department of Surgery Yale University School of Medicine</b>
<b>1994 - 1998</b>	<b>Education Committee Department of Surgery Yale University School of Medicine</b>
<b>1993 - 2004</b>	<b>Clinical Computer Workstation Committee Yale-New Haven Medical Center</b>
<b>1994 - 2004</b>	<b>Pharmacy and Therapeutics Committee Yale-New Haven Hospital</b>
<b>1993 - 1995</b>	<b>Committee of Residency Program Directors Yale-New Haven Hospital</b>
<b>1992 - 1995</b>	<b>Clinical Firm Chiefs Committee Department of Internal Medicine Yale University School of Medicine</b>
<b>1992 - 1998</b>	<b>Clinical Education Committee Department of Medicine Yale University School of Medicine</b>
<b>1988 - 1990</b>	<b>Utilization Review Committee Yale-New Haven Hospital</b>
<b>1988 - 1990</b>	<b>Quality Assurance Committee Yale-New Haven Hospital</b>
<b>1988 - 1990</b>	<b>Claims Committee (Risk Management) Yale-New Haven Hospital</b>
<b>1987 - 1989</b>	<b>Pharmacy and Therapeutics Committee Yale-New Haven Hospital</b>
<b>1987 - 1990</b>	<b>Emergency Service Advisory Committee (Chairman 1988 - 1990) Yale-New Haven Hospital</b>
<b>1987 - 1990</b>	<b>Disaster Committee (Chairman 1988 - 1990) Yale-New Haven Hospital</b>

## **Honors and Awards:**

- 1999      Emergency Medicine Residents Award for Excellence in Emergency Medicine**
- 1991      Teaching Award, Department of Internal Medicine**
- 1990      Fellow, American College of Emergency Physicians**
- 1971      M.D., Cum Laude, Yale University School of Medicine**
- 1971      Campbell Prize, Yale University School of Medicine; Highest rank in class**
- 1971      Thesis selected as one of ten best in medical school class**
- 1971      Alpha Omega Alpha Medical Honor Society**
- 1967      B.S., Magna Cum Laude, Yale College**
- 1967      Honors with Exceptional Distinction in Field of Major, Yale College**
- 1966      Phi Beta Kappa, Yale College**

July 1, 2004

## **Publications:**

1. **Weihl, A.C., G.H. Daniels, E.C. Ridgway and F. Maloof. Thyroid function during the early phase of subacute thyroiditis. J. Clin. Endo. and Metab. 44:1107-1114, 1977.**
2. **Hier, D.B., and A.C. Weihl. Chronic hydrocephalus associated with growth hormone deficiency and short stature. Ann. Neurol. 2:246-248, 1977.**
3. **Weihl, A.C. Endocrine responses to elevated ambient pressure. In: Proc. of Satellite Sympo. on Environmental Endocrinology. XXVII Internl. Physiol. Congr. Pub. Springer-Verlag, 1977.**
4. **Re, R.N., I.A. Kourides, A.C. Weihl and F. Maloof. Relationship between endogenous hyper-prolactinemia and plasma aldosterone. Clin. Endocr. 10 (2):187-193, 1979.**
5. **Weihl, A.C., H.C. Langworthy, R.P. Layton, P.F. Hoar and L.W. Raymond. Metabolic responses of resting divers immersed in 25.5 C. and 33 C. water. Unders. Biom. 5 (1):31-31, 1978.**
6. **Robertson, C.H., A.C. Weihl and M.E. Bradley. Plasma catechol changes on intermittent positive pressure breathing with positive end -expiratory pressure. Ann. R. Resp. D. 117 (4):385, 1978.**
7. **Weihl, A.C., H.C. Langworthy, A.R. Manalays and R.P. Layton. Metabolic responses of resting man immersed in 25.5 C. 33 C. water. Aviat. Sp. En. 52 (2): 88-91, 1981.**
8. **Ragosta, M., A.C. Weihl and L.E. Rosenfeld. A potentially fatal interaction between erythromycin and disopyramide. Am. J. Med 86 (4): 465-466, 1989.**
9. **Newton, E. and A.C. Weihl. Emergency Department Treatment of Alcohol Abuse: Impact On Availability of Emergency Services. Ann. Emerg. Med. 19(4):495 abst., 1990**